

DEC - 5 2000

K003291

**Bayer Diagnostics**  
**ACS:180 and ADVIA Centaur anti-TPO Immunoassays**  
**Summary of Safety and Effectiveness**

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

**1. Submitter Information**

Contact person: William J. Pignato

Address: Bayer Diagnostics Corporation  
63 North Street  
Medfield, MA 02052

Phone: (508) 359-3825  
FAX: (508) 359-3356  
e-mail: william.pignato.b@bayer.com

Date Summary Prepared: October 13, 2000

**2. Device Information**

Proprietary Name: ADVIA Centaur and ACS: 180 anti-TPO  
Immunoassay

Common Name: anti-TPO Immunoassay

Classification Name: Thyroid autoantibody immunological test system

Class: Class II

CFR: 21 CFR 866.5870

Product Code: JZO

**3. Predicate Device Information**

Name: DYNOTest® anti-TPO<sub>n</sub>

Manufacturer: BRAHMS Diagnostica, GmbH  
Neuendorfstrasse 25  
D-16761 Hennigsdorf Germany

510(k) Number: K992791

**4. Device Description**

The ACS:180 anti-TPO is a competitive chemiluminescence immunoassay intended for the quantitative determination of autoantibodies against thyroid peroxidase in human serum and

plasma. A mouse monoclonal antibody against thyroid peroxidase bound to the solid phase competes with autoimmune anti-thyroid peroxidase antibodies in patient samples, standards, and controls for indirectly labeled native human thyroid peroxidase in the reagent. The indirect label consists of a chemiluminescent labeled (acridinium ester) monoclonal antibody against a separate epitope on the added thyroid peroxidase. Following incubation, unreacted labeled thyroid peroxidase and unreacted antibodies from the sample are washed from the reaction mixture. The chemiluminescence of the reacted, labeled thyroid peroxidase is measured in a luminometer. The measured chemiluminescence is inversely proportional to the quantity of anti-thyroid peroxidase antibody in the sample.

## **5. Statement of Intended Use**

The ACS:180 and ADVIA Centaur anti-TPO Immunoassays are competitive, chemiluminescence immunoassays for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum or plasma for use on the ACS:180 and ADVIA Centaur automated analyzers marketed by Bayer Corporation. The anti-TPO Immunoassay is used as an aid in the diagnosis of Hashimoto's and Graves' disease, autoimmune diseases affecting the thyroid gland.

## **6. Summary of Technological Characteristics**

The ACS:180 and ADVIA Centaur anti-TPO Immunoassays are similar to the BRAHMS Diagnostica DYNOTest® anti-TPO kit (K992791) in the indications for use, format, solid phase, performance characteristics, and results. The ACS:180 and ADVIA Centaur anti-TPO tests differ mainly in their intended use on an automated analyzer as compared to a manual coated tube technique. In the automated method, a chemiluminogenic molecule (acridinium ester) is used to replace the <sup>125</sup>I signal used in the DYNOTest anti-TPO manual assay.

## **7. Method Comparison**

### **Equivalence to Predicate Device**

Substantial equivalence to the DYNOTest kit, cleared under K992791, is based on clinical comparison using 530 serum samples from normal blood donors (n=253) and patients with Graves' disease and Hashimoto's thyroiditis (n=277). Overall agreement of both groups based on a 2 X 2 agreement table was 528/530 = 99.6%.

Normal patients:

		<b>DYNOTest anti-TPO</b>	
		Positive	Negative
<b>ACS:180</b>	Positive	28	0
	Negative	0	225

% Agreement = 100.0

Graves patients:

		<b>DYNOTest anti-TPO</b>	
		Positive	Negative
<b>ACS:180</b>	Positive	64	1
	Negative	0	29

% Agreement = 98.9

Hashimoto's patients:

		<b>DYNOTest anti-TPO</b>	
		Positive	Negative
<b>ACS:180</b>	Positive	173	1
	Negative	0	9

% Agreement = 99.5

Overall Agreement: 528/530 = 99.6 %

This correlation study demonstrates that the ACS:180 anti-TPO assay is substantially equivalent to the legally marketed predicate device, the BRAHMS Diagnostica DYNOTest anti-TPO assay.

### **ADVIA Centaur**

For 149 serum samples in the range of 0 to 3000 U/mL, the relationship between the ADVIA Centaur anti-TPO assay and the ACS:180 anti-TPO assay is described by the equation:

$$\text{ADVIA Centaur anti-TPO} = 1.05 (\text{ACS:180 anti-TPO}) - 15.1 \text{ U/mL}$$

Correlation coefficient (r) = 0.981

The diagnostic concordance between the two assays is shown in the following table:

<b>Category</b>	<b>ACS:180 Positive</b>	<b>ACS:180 Negative</b>
<b>ADVIA Centaur Positive</b>	75	4
<b>ADVIA Centaur Negative</b>	0	70

Agreement: 145 / 149 = 97.3 %



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 5 2000

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. William J. Pignato  
Director of Regulatory Affairs  
Bayer Corporation  
63 North Street  
Medfield, Massachusetts 02052-1688

Re: K003291  
Trade Name: Bayer Diagnostics ACS: 180 and ADVIA: Centaur Anti-TPO Assay  
Regulatory Class: II  
Product Code: JZO  
Dated: October 13, 2000  
Received: October 20, 2000

Dear Mr. Pignato:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

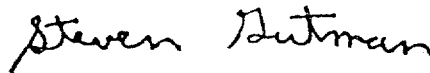
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

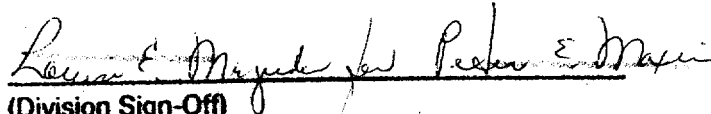
Enclosure

510(k) Number (if known): K003291

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur anti-TPO Assay

**Indications for Use:**

The ACS:180 and ADVIA Centaur anti-TPO Immunoassays are competitive, chemiluminescence immunoassays for the quantitative determination of autoantibodies to thyroid peroxidase (TPO) in human serum or plasma for use on the ACS:180 and ADVIA Centaur automated analyzers marketed by Bayer Corporation. The anti-TPO Immunoassay is used as an aid in the diagnosis of Hashimoto's and Graves' disease, autoimmune diseases affecting the thyroid gland.

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K003291

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)